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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,955	11/26/2003	Ruoping Chen	AREN-007CON2(7.US29.CON)	3273

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EXAMINER
LI, RUIXIANG

ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
03/10/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/723,955	CHEN ET AL.	
	Examiner	Art Unit	
	RUIXIANG LI	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *69-87* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *69-87* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/11/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/11/2009 has been entered. Claims 69-87 are pending and under consideration.

Withdrawn Objections and/or Rejections

The rejection of claims 33-35 and 51-68 under 35 U.S.C. 112, second paragraph is withdrawn.

The rejection of claims 69-87 under 35 U.S.C. 112, 1st paragraph for written description is withdrawn.

Information Disclosure Statement

The information disclosure statement filed on 11/11/2009 has been considered by the Examiner and a signed copy of the form PTO-1449 is attached to the office action.

Claim Rejections under 35 USC § 101 and 112, 1st paragraph

(i). 35 U.S.C. 101 reads as follows:

(ii). Claims 69-87 are rejected under 35 U.S.C. 101 and 112, first paragraph because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. The basis for the rejection is set forth in the previous office action.

Claims 69-87 are drawn to a method of screening for a compound that increases cAMP levels in peripheral blood leukocytes. The claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. A specific and substantial utility is one that is particular to the subject matter claimed and that identifies a "real world" context of use for the claimed invention which does not require further research.

First, since the claims are directed to a specific method of use, the utility of the claims are limited to that use. Consequently, there is no "well-established" utility for the method (See REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS, Example 12, on page 63. http://www.uspto.gov/web/patents/guides.htm)

Secondly, there is no specific and substantial utility for the orphan human TDAG8 receptor of SEQ ID NO: 82, the compound to be identified by the method, and thus a method of screening for a compound. The human TDAG8 receptor of SEQ ID NO: 82 is

an orphan receptor and has no known ligand and is not linked to any known biological functions, any known diseases or medical conditions. It clearly requires further research for an artisan to confirm a "real world" context of use, that is, to determine the biological functions of the orphan human TDAG8 receptor used in the screening method of the present invention and a use for the compound to be identified by the claimed screening method in a patent sense.

Furthermore, MPEP§2107.01 clearly lists that a method of assaying for or identifying a material that itself has no specific and/or substantial utility does not have a specific and substantial utility.

Accordingly, the rejections of claims 69-87 under 35 U.S.C. 101 & 112, 1st paragraph due to lack of a patentable utility are maintained.

(iii). Response to Applicants' argument

On the 2nd paragraph of page 7 of Applicants' response, Applicants argue that the specification clearly states that TDAG8 is a human T-cell death receptor (page 3, lines 23-24) and that there is a strong correlation between apoptosis and TDAG8 (page 3, line 28). Applicants also argue that the role of TDAG8 in T cell apoptosis was known before the filing date of the instant application.

Applicants' argument has been fully considered, but is not deemed to be persuasive for the following reasons. First, the specification discloses that the present invention relates

to a human T-cell death-associated gene receptor, rather than a human T-cell death. Secondly, the specification discloses that there is a strong correlation between apoptosis and TDAG8, i.e., an increase in apoptosis results in an increase in the expression of TDAG8. However, it is unknown whether an increase TDAG8 expression causes T-cell mediated apoptosis, or if such expression is a result of such apoptosis (page 3, last paragraph). The specification further discloses that the endogenous ligand forTDAG8 is unknown and is thus considered an orphan GPCR (page 4, lines 1-2). Moreover, there is no evidence on the record showing that the orphan human TDAG8 of SEQ ID NO: 82 has a particular role in T cell apoptosis. Clearly, it requires further research for an artisan to confirm a "real world" context of use, that is, to determine the biological functions of the orphan human TDGA8 receptor of SEQ ID NO: 82 and thus a specific and substantial utility for the compound to be identified by the instantly claimed method.

On the 3rd paragraph of page 7 of Applicants' response, Applicants argue that knowledge of a GPCR's natural ligand is simply not necessary for establishing a useful function for such a receptor. Applicants argue that it is possible to know a receptor's function and develop and market pharmaceutical agents targeting it without any understanding of the natural ligand. Applicants argue that because orphan GPCRs have been characterized and found useful, even in the absence of a known endogenous ligand, a method for identifying modulatory compounds for such functionally-

characterized orphan GPCRs represent a specific, substantial "real world" use of the claimed method.

Applicants' argument has been fully considered, but is not deemed to be persuasive because the specification fails to disclose a biological function of the orphan human TDAG8 of SEQ ID NO: 82 and fails to provide a specific and substantial utility for the orphan human TDAG8 of SEQ ID NO: 82, the compound to be identified by the claimed method, and thus the instantly claimed method for the reasons set forth above.

Accordingly, the rejections of claims 69-87 under 35 U.S.C. 101 & 112, 1st paragraph due to lack of a patentable utility are maintained.

Conclusion

No claims are allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

/Ruixiang Li/
Primary Examiner, Art Unit 1646

Ruixiang Li, Ph.D.
March 6, 2010